OCT 0 8 2008

510(k) Summary

Date:	29 September 2008
Submitter:	Osypka Medical, Inc. 7855 Ivanhoe Avenue, Suite 226, La Jolla, CA 92037
Contact Person:	Markus Osypka, Ph.D., President Osypka Medical, Inc. 7855 Ivanhoe Avenue, Suite 226, La Jolla, California 92037 Phone: (858) 454 0021 Fax: (858) 454 0064
Device Trade Names:	CARDIOTRONIC® ICON® OSYPKA MEDICAL® ICON® All of Type (Version) C3
Common / Usual Names:	Hemodynamic Monitor, Cardiac Output Monitor, Cardiovascular Monitor
Classification Names:	21 CFR 870.2770 Impedance Plethysmograph
Regulatory Class:	Class II
Product Code:	DSB
Predicate Device:	K081035 AESCULON® Type (Version) C2, further referred to as the AESCULON®

Device Description:	The ICON® is a noninvasive cardiac output monitor, also known as a hemodynamic monitor. By application of an array of adhesive ECG type surface electrode to the body, the ICON® measures thoracic electrical bioimpedance (TEB) and in particular the changes of bioimpedance related to the cardiac cycle. The ICON® determines hemodynamic parameters related to blood flow, contractility and fluid status.
Intended Use:	The ICON® is intended for noninvasive continuous monitoring of hemodynamic parameters for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments under the care of a physician, nurse or medical technician.
Technology:	The ICON®, including the option Pacemaker Clinic®, is substantially equivalent to the predicate device AESCULON® in terms of design, intended use and principal of operation. Measurement of thoracic electrical bioimpedance (TEB) and recording of the ECG is accomplished by attaching an array of ECG type surface electrodes to the patient. A high frequency, low amplitude patient auxiliary current is applied via the outer electrodes and the resulting voltage and the ECG is recorded between the inner electrodes. For the estimation of stroke volume (SV) the ICON® (new device) and AESCULON® (predicate device) use the general relationship $SV = V_{EPT} \cdot \bar{v}_{FT} \cdot FT$ with V_{EPT} being the volume of electrically participating tissue, $\bar{v}_{FT}$ being the mean blood velocity during flow time, and FT being the left ventricular flow time. Both the ICON® (new device) and the AESCULON® (predicate device) derive from the measurement of TEB § the base impedance Z_0, § the magnitude of the maximum rate of change of impedance $\left\lvert \left(\frac{dZ(t)}{dt} \right)_{MIN} \right\rvert$, and § the left-ventricular flow time FT.

Theory / SV Algorithm	The ICON® (new device) and AESCULON® (predicate device) do not differ in the theoretical model applied to the measurement of the magnitude of the maximum rate of change of impedance $\left\lvert\left(\frac{dZ(t)}{dt}\right)_{MIN}\right\rvert$, which relates this magnitude to peak aortic blood acceleration. The ICON® (new device) and the AESCULON® (predicate device) derive thereof an index of contractility.
Options:	Unlike the AESCULON® (predicate device), the ICON® (new device) does not provide the options incorporating a module and accessories for measurement of noninvasive blood pressure (NIBP) and pulse oximetry (SpO_2).
Summary Non-Clinical Testing:	Demonstration of substantial equivalence between the ICON® (new device) and the AESCULON® (predicate device) was based on an assessment of non-clinical performance data.
Summary Clinical Testing:	Clinical testing not part of this submission.
Conclusion:	It is concluded that the ICON® is as safe, as effective, and performs as well as the AESCULON® (predicate device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Osypka Medical, Inc.
c/o Markus Osypka, PhD
President
7855 Ivanhoe Avenue, Suite 226
La Jolla, CA 92037

Re: K082242
Trade/Device Name: ICON Model C3
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: September 19, 2008
Received: September 22, 2008

Dear Dr. Osypka

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082242

Indications for Use

510(k) Number: K082242

Device Name: ICON® Type C3

Indications for Use:

The ICON® is intended for noninvasive continuous monitoring of hemodynamic parameters for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments under the care of a physician, nurse or medical technician.

Prescription Use X AND / OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BZuckerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K08 2242